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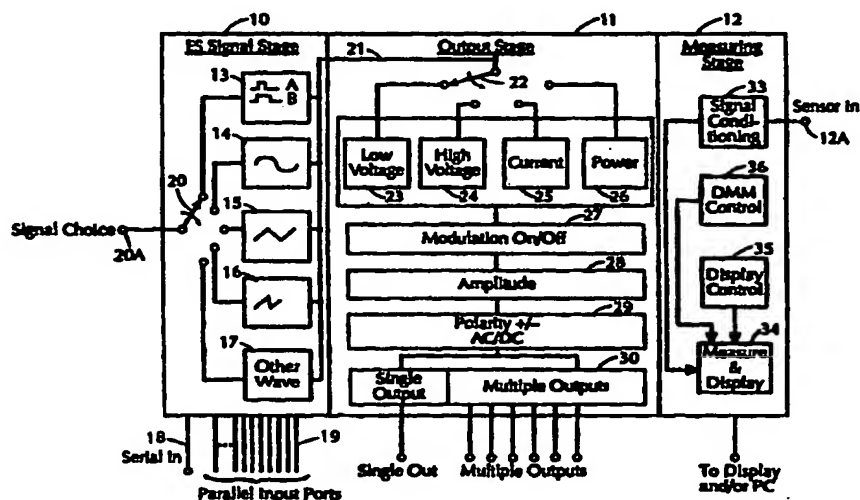
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(54) Title: MULTI-FUNCTIONAL ELECTRICAL STIMULATION SYSTEM



(57) Abstract

The present invention is a multi-functional electrical stimulation (ES) system adapted to yield output signals for effecting faradic, electromagnetic or other forms of electrical stimulation for a broad spectrum of different biological, and biomedical applications. The system includes an ES signal stage (10) having a selector (20) coupled to a plurality of different signal generators (13-17), each generator producing a signal having a distinct shape such as a sine, a square or sawtooth wave, the parameters of which are adjustable in regard to amplitude, duration, repetition rate, and other variables. Also included in the system is a measuring stage (12) which measures, and displays the electrical stimulation signal operating on the substance being treated as well as the outputs of various sensors which sense conditions prevailing in this substance whereby the user of the system can adjust it to yield an electrical stimulation signal of whatever type he wishes, and can then observe the effects of this signal on a substance being treated.

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MULTIFUNCTIONAL ELECTRICAL STIMULATION SYSTEMRelated Applications:

5 This application is related to our provisional application S.N. 60/034,869, filed on January 27, 1997, entitled "ELECTRICAL STIMULATOR AND AMPLIFIER", the entire disclosure of which is incorporated herein by reference.

10 BACKGROUND OF INVENTION

Field of Invention:

 This invention relates generally to the electrical stimulation devices for effecting faradic, electromagnetic or other forms of electrical stimulation, and more particularly, to a multi-functional system for this purpose capable of selectively yielding electrical stimulation signals for a broad spectrum of different biological and bio-medical applications as well as for other applications, such as electrophoresis.

20 Status of Prior Art:

 Electrical stimulation (ES) is widely used in biological and bio-medical research as well as in diagnostics and in clinical treatment. In faradic stimulation an intermittent or alternating current is produced, whereas in electromagnetic stimulation, a current passing through a coil produces an electromagnetic field whose pattern depends on the wave form of the current.

30 Electrical stimulation is employed to effect nerve regeneration, in neuromuscular research, in medical diagnosis and treatment, and in pulsed voltage electrophoresis. Such stimulation is also used in bone healing and in wound healing, in pain relief by means of transcutaneous electrical nerve stimulation (TENS).
35 The use of ES to effect nerve regeneration is disclosed

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in the Zanakis et al. patent 4,774,967 as well as in the Borgens patent 4,919,140.

5 Researchers in the biological and medical sciences, physiotherapists, and clinicians who make use of ES require electrical stimulators of a type suitable for the activities in which they are engaged. Thus neurological investigators who seek to non-invasively stimulate deep nerves make use of commercially available magnetic stimulators which produce a high-
10 intensity magnetic field pulse for this purpose.

Also commercially available are constant current stimulators for direct cortical stimulation as well as electrical stimulators for nerve and muscle stimulation procedures which generate single or double pulses, or
15 trains of such pulses. And commercially available are wave generators capable of selectively generating sine and square wave pulses suitable for other types of electrical stimulation.

But what is not available to researchers and
20 others who make use of electrical stimulation is a multi-functional system capable of yielding an electrical stimulation signal that is appropriate for whatever biological or biomedical application is the concern of the user of the system.

25 Let us assume, by way of example, that a researcher is engaged in a neurological research program in the course of which it becomes necessary to

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conduct tests on the effects of many different types of electrical stimuli on a certain set of nerves. The researcher would then have to assemble from different commercial sources the several electrical stimulators of different types called for by this program. This
5 burdensome requirement adds substantially to the cost of conducting this research and to its space demands.

While the invention will be described herein as a system for producing electrical stimulating signals, the signals produced thereby can also be used for
10 electroporation, electrophoresis (preferably pulsed voltage electrophoresis) and iontophoresis as well as for electrochemical applications as in the treatment of cancer in which a current is passed through the tissue being treated. The signals can also be used to
15 transdermal drug delivery.

SUMMARY OF INVENTION

In view of the foregoing, the main object of this invention is to provide a multi-functional electrical stimulation (ES) system adapted to yield output signals
20 for effecting faradic, electromagnetic or other forms of electrical stimulation for a broad spectrum of different biological and bio-medical applications.

A significant advantage of a system in accordance with the invention is that it affords its user, whether
25 a researcher, a diagnostician or a clinician, with

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whatever electrical stimulation signal is dictated by the specific type of electrical stimulation that is required. Thus if in conducting tests, a researcher needs to subject certain nerves to many different forms of electrical stimulation, the self-sufficient system, by itself and without accessories, is capable of supplying whatever electrical stimulation signals are appropriate.

Also an object of this invention is to provide a multi-functional system of the above type that includes a measuring stage that measures and displays the electrical stimulation signal operating on the substance being treated and also indicates and displays signals issuing from sensors which sense conditions prevailing in the substance, such as pH and O₂, whereby the user of the system is able to observe and monitor the effects of the electrical stimulation signal he has selected.

Another object of this invention is to provide a highly-compact system of the above type which can be manufactured at relatively low cost.

Briefly stated, these objects are attained by a multi-functional electrical stimulation (ES) system adapted to yield output signals for effecting faradic, electromagnetic or other forms of electrical stimulation for a broad spectrum of different

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biological and bio-medical applications. The system includes an ES signal stage having a selector coupled to a plurality of different signal generators, each producing a signal having a distinct shape such as a sine, a square or sawtooth wave, the parameters of which are adjustable in regard to amplitude, duration, repetition rate and other variables.

The signal from the selected generator in the ES stage is fed to at least one output stage where it is processed to produce a high or low voltage or current output of a desired polarity whereby the output stage is capable of yielding an electrical stimulation signal appropriate for its intended application. Also included in the system is a measuring stage which measures and displays the electrical stimulation signal operating on the substance being treated as well as the outputs of various sensors which sense conditions prevailing in this substance whereby the user of the system can manually adjust it or have it automatically adjusted by feedback to provide an electrical stimulation signal of whatever type he wishes and the user can then observe the effect of this signal on a substance being treated.

In another embodiment of the system, the signals from the ES signal stage are put on a bus from which they can be accessed by the output stages.

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The electrical stimulation signal yielded by the system can be used for applications other than those involving electrical stimulation, such as for electrophoresis and electroporation. Or the signals from the system can be used in applications requiring mechanical or acoustic waves by applying the signal to an appropriate transducer.

BRIEF DESCRIPTION OF DRAWING

For a better understanding of the invention, as well as other objects and further features thereof, reference is made to the following detailed description to be read in conjunction with the accompanying drawing, wherein:

Fig. 1 is a block diagram of a system in accordance with the invention having an ES stage, an output stage and a measuring stage;

Fig. 2 is a block diagram of a basic version of a system for producing various electrical stimulation pulses;

Fig. 3 illustrates an example of a preset custom module;

Fig. 4A is a graph showing at the full power output of an amplifier a pulse having a rising edge;

Fig. 4B is a graph showing at the full power output of an amplifier a pulse having a falling edge; and

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Fig. 5 and Fig. 6 shows an embodiment of a low voltage output stage for generating various analog pulses and their combinations from digital inputs.

DETAILED DESCRIPTION OF INVENTION

5 A system in accordance with the invention, as shown in Fig. 1, is composed of an ES signal stage 10 which at the user's discretion generates a faradic, an electromagnetic or other types of electrical stimulation signal which is fed to an output stage 11.
10 Output stage 11 processes the electrical stimulation signals selected by the user to yield a stimulation signal suitable for its intended biological or biomedical application.

Also provided is a measuring stage 12 which
15 measures and displays the electrical stimulation signal operating on the animal or human substance being subjected thereto, and/or its electrical parameters as well as the output of various sensors which sense conditions prevailing in this substance whereby the
20 user is able to observe and monitor the effects of the stimulation signal he has selected on the substance being treated.

ES signal stage 10 includes signal generators 13 to 17 producing signals of different shape. Generator
25 13 is a pulse wave generator generating one or more rectangular pulses, such as pulses A and B of different

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width which can be outputted separately or can be added or subtracted from each other to yield A or B, A plus B or A minus B. Generator 14 is a sine wave generator, generator 15 generates a triangular or sawtooth wave, and generator 16 produces a ramp voltage wave. Generator 17 yields a wave of any arbitrary shape. The signal generators are capable of generating a minimum one pulse signal or a greater numbers of pulse signals, or of generating a gated signal with a minimum of one period or a greater number of periods, with individual adjustments of electrical parameters.

By means of a serial input port 18 to E-S stage 10 or a set of parallel input ports 19, the parameters of the respective waves produced by signal generators 13 to 17 can be adjusted in frequency, pulse width, amplitude and repetition rate, or with respect to any other variable. Coupled to generators 13 to 17 and activated by a trigger signal applied thereto at terminal 20A is a mechanical or electronic multi-contact selector switch 20. The output signal from the signal generator selected by a switch 20 is applied through a line 21 to output stage 11. In practice, the line is preferably a bus system.

The ES signal stage 10 is preferably miniaturized and may take the form of a hybrid device or a single ASIC chip (Special Application Integrated Circuit).

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Output stage 11 includes a mechanical or electronic selector switch 22 which applies the ES signal from stage 10 either to a low voltage processor 23, a high voltage processor 24, a current processor 25, or a power processor 26 to put the ES signal in a form appropriate to the intended application for electrical stimulation. In a preferred version, all signals can be accessed simultaneously by one or more output stages through a system bus. In practice, a combination of one or more signal generators in the ES signal stage with one or more of the output stages can be miniaturized.

The output of the processor 23, 24, 25 or 26 chosen by selector switch 22 is fed to a modulator 27 coupled to an amplitude control unit 28 which modifies the amplitude of the pulse signal applied thereto. The output of amplitude-control unit 28 is applied to a polarity control unit 29 in which the electrical stimulation signal is given a positive or negative polarity or is converted to an a-c signal, depending on the intended application for the electrical stimulation signal.

Each output stage can be configured with either multiple output terminals 30 or with a single output. The multiple outlets make it possible to run several parallel experiments or processes concurrently.

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As previously mentioned, the ES system can be miniaturized to form a single ES component comprising a digital pulse generator ASIC and miniaturized analog circuitry packaged together. A functional sketch of such ES component 31 is shown in Fig. 2, and an example of a customized module 32 with a preset waveform and preset electrical parameters is shown in Fig. 3.

A preferred version of the ES component includes a sophisticated digital pulse generator on a chip and an analog circuitry to define complex pulse patterns, with amplitudes up to $\pm 10V$. The output can be fed into any number of desirable output stage, which can be integrated into the same component or be independent proprietary devices, e.g., voltage controlled or current controlled output stages with various voltage/current amplitudes, high frequency output stage with various bandwidths depending on a specific application, various power output stages, etc. Waveforms other than pulse patterns, as well as modulated signals can be part of such a "system on a chip."

The design of a digital ASIC consists of several blocks, which can be either used together to create a sophisticated pulse generator for biomedical applications, or can be used in any number of other designs requiring a pulse signal. Each of these blocks

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or functional modules can provide an independent waveform or pulse (A pulse; B pulse; square wave; time delay; etc). A basic one output version of the signal generator delivers two independent pulses A and B with
5 digitally adjustable pulse widths, the same pulse repetition rate, and with an adjustable delay between them. It also delivers a square wave and timing for alternate and biphasic pulses. In a two or more output version, individual pulses can have independently set
10 repetition rates.

Several of these independent signal generators on the ASIC can be combined into a multi-output device. All timing parameters of the pulses preferably are fully programmable by a user via hardware or via
15 software-generated inputs to the ASIC. For example, one can adjust timing using thumbwheels or switches connected via parallel inputs of the ES component, or by using software and a serial, parallel, or custom interface as an input to the ASIC (or a combination of
20 analog and digital inputs can be used). The ES component can include both a parallel and a serial interface so that the user can define the optimal means for each application.

The analog output amplitudes of the ES component or ES system can be adjusted for each pulse separately
25 (via hardware or software, as above). At the same

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time, a specific d-c level can be added; i.e., signal can be shifted up or down from zero line. The alternate and biphasic pulses are designed so that only one adjustment for both positive and negative pulse width and amplitude is required, which results in guaranteed symmetrical signals.

In the circuits shown in Figs. 5 and 6, the output of the ES component preferably varies from 0 to ± 10 V and is set digitally. Rise time and fall time for a full power response in a standard speed implementation is 336 ns and 360 ns, respectively (see Figs. 4A and 4B). For a 1.0 V pulse response, the corresponding numbers are 186 ns and 163 ns, respectively. The ES component can be also interfaced to a current output stage with single or multiple outputs and current levels of $\pm 200 \mu\text{A}$ (based on the resistor values/setting in Fig. 5), or another current level depending upon the particular application of use requires other resistor values. In practice an isolated power supply for both analog and digital signals can be used.

An optional galvanic isolation can be added between the digital and analog parts of the ES component using standard electronic components. This isolation system, in combination with an isolated power supply for the analog signals, provides an isolated output from the stimulator.

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Pulse Generation:

This aspect of the invention is a detailed solution for generating fast, high accuracy analog pulses with predefined pulse amplitudes, as well as for combining at least two single pulses to a pulse pattern. It is one of possible specific solutions which can be implemented as a part of the overall system design. The "Inputs and Outputs" section below can be viewed as a design example to show the concept behind creating an analog pulse pattern based on at least two pulse signals A and B. Each of the A and B pulses has a separate setting of the pulse width and pulse amplitude. The same concept is used to create a highly accurate biphasic or alternating pulses based on a single amplitude setting for both positive and negative part of the signal and thus eliminating the risk for an unbalanced charge delivered to the experimental system.

Digital pulses A and B have a pulse width T_A and T_B and a delay T_D between them generated in hardware (or software) and together with the d-c voltages preset to the desired amplitudes for each pulse signal constitute the input signals to this stage. The design depicted in the "Inputs and Outputs" section uses a voltage reference and two 12-bit DACs on the same chip to set carefully controlled d-c levels. The digital

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pulses A and B are used to control opening and closing of a switch on the output of each of the DACs, respectively, and thus shaping A and B pulse waves. The correct amplitudes are set by the DACs and the correct analog pulse width is set by the length of time the appropriate analog switch is closed. When the switch is open, the output voltage for A and B pulse, respectively, is set to zero. Both waveforms are then passed through an adding circuitry. A d-c level can be added at the same time.

An optional set of preprogrammed modules, based on the architecture of the basic ES component, can be used independently or added to the basic ES component or even made a part of the ASIC design; for example, a pulse train used clinically for bone healing (timing parameters; repetition rate - 15Hz, pulse train length - 5ms, positive pulse with -200 us, negative pulse width - 24 us, Electro-Biology, Inc. Parsippany, N.J.). This conventional bone-healing signal, measured with a pick-up coil, is delivered from an electromagnetic field (EMF) stimulator. A preprogrammed ES module allows for testing of the biological effects of the same or a similar electrical signal, but delivered through electrodes, without a strong magnetic field component, in addition to or instead of both experimental and clinical use in EMF stimulators. In

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situations with multiple parallel experiments, the cost of the equipment presently required will be significantly reduced by using pulse generator ASIC-based system of this invention rather than buying several independent stimulators.

The flexible pulse generator ASIC and the ES component of this invention can form the basis for an ES device as described herein, and can be used by electrical stimulation equipment manufacturers as an inexpensive off-the-shelf component to simplify production, cut costs, save space, and miniaturize existing systems. The present invention improves the overall system reliability by providing the whole system as a single well-tested component. The present invention using an ASIC reduces the power requirements, thus permitting battery operation in applications where high current/voltage output is not required, which also allows for a further miniaturization of the total digital/analog system and adds a safety feature for clinical applications.

The following are examples of signal generators that can be incorporated in the ES signal stage 10, and the respective variable timing parameters of these generators:

I. Pulser Generator

- (a) Square pulse - repetition rate (50% duty cycle)

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- 5 (b) Single pulse A - repetition rate & pulse width
- (c) Dual pulses A and B - individually set pulse width
single output: same repetition
rate for both A and B dual
outputs: same or individually
set repetition rates
- 10 (d) Alternated pulse - set by setting pulse A
parameters, rest automatically
- (e) Biphasic pulse - set by setting pulse A
parameters, rest automatically
- 15 (f) A + B - same repetition rate for both,
individual pulse widths
- (g) A - B - same repetition rate for both,
individual pulse widths
- 20 (h) Pulse train - repetition rate of pulse train,
and either pulse width of the
pulse train or number of
individual pulses in the train
- 25 (i) User defined pulse form - all applicable timing
parameters
- 30 II. Sinewave generator - frequency
- III. Sawtooth, triangle, ramp waveform generators - frequency, rise and fall
time
- 35 Arbitrary waveform generator - all timing parameters

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Inputs and Outputs:

Referring now to Fig. 5, there are two, 2mm, 40 pin headers (P1 and P2) from which signal inputs, signal outputs, and power connect to the printed circuit board (pcb). The board requires two supplies to operate, +15VDC and -15VDC. Power and Ground comes in through P2. +5VDC necessary for logic circuitry and interface is derived from onboard regulator U15 from the +15VDC supply.

Pulse waveforms are generated within the stimulator by appropriate switching of 8 to 1 multiplexers U1, U2, U17, and U3. Logic level pulses TA, TB, SQ, TA1, and TA2 are selected by addressing U1 and U2 with signals WV-A, WV-B, and WV-C. U17 and U17 and U# sets pulse polarity and selects between UA and UB amplitudes.

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TABLE 1

WV-A	WV-A	WV-C	PULSE	AMPLITUDE
0	0	0	Constant "'ON"	Constant UB
0	0	1	TA, "0"	Pulsed TA=UA
0	1	0	TB, "0"	Pulsed TB=UB
0	1	1	TA, TA2	Pulsed TA=UA, TA2=-UA
1	0	0	TA, TA1	Pulsed TA=UA, TA1=-UA
1	0	1	TA, TB	Pulsed TA=UA, TB=-UB
1	1	0	TA, TB	Pulsed TA=UA, TB=UB
1	1	1	SQ, "0"	Pulsed SQ=UA

U4 and U5 comprise the "logic" which creates the waveform and routes the resultant signal to the output amplifiers. When the output of U1 pin 8 is high, switch 1 of U5 is enabled, presenting the level determined by U17 to the output amplifiers, This also breaks switch 2 of U5 which prevents contention with the output of U3. The level determined by t-T3 pin 8 is presented to the output amplifiers when U1 pin 8 is low and U2 pin 8 is high. When

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U1 pin 8 and U2 pin 8 are low, corresponding to no pulses, switch 4 of U5 is enabled, thereby shorting the input of the output amplifiers to ground. This discharges or resets the node to 0 VDC.

5 Output Amplifiers:

 The dual operation amplifier IC, U9, and associated passive components comprise the output amplifiers. Pin 2 of U9 is a summing junction. Pulses described above induce current through R3 into the inverting node of the first
10 amplifier (pin 2). If d-c level is set, d-c voltage appearing at the junction of R4 and U8 pin 14 induces a d-c current into the same inverting junction thereby creating a d-c voltage bias level at the output. If DC-level is not set, R4 is grounded through switch 2 of U8. No d-c bias
15 appears at the output in this case. OUT1 is the output of the first operational amplifier. This represents the inverted pulsed signal output train. The second amplifier of U9 is also an inverter which provides a non-inverted pulse train. Switches 3 and 4 of U8 allow for the polarity
20 selection of OUT 2. A logic low selects the non-inverting

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output. A logic high selects the inverted output. Upon selecting the inverting output illuminates LED1.

D-C Level Circuits (Fig. 6):

A 14 bit multiplying DAC, U6, operational amplifier U7,
5 and associated passive components form the d-c level
circuit. U6 is a current output DAC configured for bipolar
output. The VREF input is determined by the level of UA.
Since UA ranges from 0 to +10V, the d-c level circuit can
range from 0VDC to ± 10 VDC. The 14-bit DAC bus interfaces
10 directly to P1. Three control signals LVLDAC/LDAC,
LVLDAC/CS, and LVLDAC/WR allow for addressing the DAC and
writing levels. Refer to the AD75538 data sheet, for more
detailed information on this part.

Dual Programmable Reference:

15 Referring now to Fig. 6, U14 is an accurate and stable
+10,00 volt reference. Resistors R16 through R29 form a
precision resistive divider to derive 6 other voltage
levels. U10 and U11 allow for the selection of +10,00V,
5.000V, 1.000V, 0.3000V, 0.2000V, 0.1000V, 0.0100V or ground
20 for the UA and UB channels. Signals UA-A0, UA-A1, UA-A2,

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UB-A0, UB-A1, and UB-A2 determine the UA and UB reference levels respectively.

TABLE 2

5

10

15

UA-A0	UA-A1	UA-U2	LEVEL
0	0	0	10.00V
0	0	1	5.000V
0	1	0	1.000V
0	1	1	0.3000V
1	0	0	0.2000V
1	0	1	0.1000V
1	1	0	0.0100V
1	1	1	0.0000V

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TABLE 3

	UB-A0	UB-A1	UB-U2	LEVEL
	0	0	0	10.00V
5	0	0	1	5.000V
	0	1	0	1.000V
	0	1	1	0.3000V
	1	0	0	0.2000V
	1	0	1	0.1000V
10	1	1	0	0.0100V
	1	1	1	0.0000V

A dual op amp, U13, converts the DAC's A channel current output to +UA and -UA voltages. Likewise, U16 converts the DAC's B channel current output to +UB and -UB voltages. U12 is a dual 12-bit multiplying DAC arranged for unipolar outputs. U12 shares the same data base as U6. It is addressed and controlled by the SAV-/CSA, SAV-/CSB, and SAV-/WRDAC signals. \pm UA and \pm UB are used by the waveform generating circuits to set signal amplitude and polarity. The UA level is also used as the reference for the level

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DAC. Please refer to the datasheets for the AD7538, AD7547, ADG408, ADG433, AD712, 78L05, and LT1235 components.

Voltage Output Stage:

A $\pm 10\text{V}$ voltage output is a generic output stage useful
5 for several neuromuscular and other applications. This
output stage preferably includes an output amplifier stage
sufficient to drive a load. A $\pm 50\text{V}$ voltage output stage can
be used in the alternative as a generic output stage useful
for several neuromuscular and other applications. It can be
10 limited to a lower voltage than the maximum $\pm 50\text{V}$ by choosing
a lower voltage power supply and changing values of
appropriate components such as resistors. This higher
voltage output stage is especially useful for the
optimization of low voltage electroporation, and it can be
15 packaged together with the ES component. Higher voltage
output stages in the range up to 250V , or even higher up to
 $1,000\text{V}$, or up to a few thousand volts (preferable about
 $6,000\text{V}$), and ranges therebetween, can be used (or can be
specially useful) for pulsed voltage electrophoresis or
20 magnetic stimulation of the brain.

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System Overview:

Referring again to Fig. 1 showing the system composed of ES stage 10, output stage 11 and measuring stage 12, in using this system the user chooses the particular signal or waveform appropriate to the intended electrical stimulation application. The user uses a dial or switches attached to the system or software communicating with the system, and sets up specific timing and amplitude parameters via the serial or parallel input ports 18 and 19. The user also selects from output stage 11 the single or multiple output ports.

Measuring stage 12, by means of sensors input terminal 12A allows the user by appropriate sensors to sense the electrical stimulation signal passing through the organic substance being treated and environmental parameters, such as current, magnetic field, voltage, impedance, temperature, pH, gas (O₂, CO₂, etc.) as well as various biochemical involved locally in the procedure where the signal is administered or at another sites.

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The various sensors for this purpose include sensing electrodes, pick-up coils, temperature-sensitive devices, magnetic probes, and biosensors, all which yield a signal which is applied to input terminal 12A this terminal is
5 connected to a signal conditioner 33 whose output is coupled to a measuring and display unit 34 whose output is fed to a video screen or other indicator. Associated with unit 34 is a display control 35 and a DMM control 36.

General System Features:

10 As ES system in accordance with the invention consists of a digital, high accuracy pulse generator capable of generating several either dependent or independent, synchronized rectangular pulses, available simultaneously, preferably on a system bus. One or more output stages
15 (identical or different) can be placed anywhere on the system bus and be accessed by a user. The choice the user makes may be threefold; either one specific output stage is plugged into the system; a specific output stage is selected among several output stages available using either a dial, a
20 selector, or other means; or several output stages are used

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in parallel, either independently or triggered by each other.

The ES system can be also triggered by an external process or event, e.g., a physiological event, and will
5 deliver either a preset signal in response to such a stimuli, or a signal which can be continuously modified by a triggering signal with respect to both timing and amplitude (and possibly shape). A preset delay between a triggering signal and a response signal can be made available.

10 Signals other than pulses can also be made available and accessible either through a selector or on the bus, including gated and/or modulated signals of various shapes. All of the signals can be fed to the output stages in the following ways: one signal to one output stage (with a
15 single or multiple outputs); one signal to several output stages (identical or different); several signals to one output stage (for a complex signal shape as in case of multiple outputs); several signals to several output stages (identical or different).

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Several, single or complex rectangular pulses and other signals are available, for the output stages, preferably on the bus. These signals are synchronized and can be accessed by an output stage either by selecting only one signal or by
5 accessing several signals at the same time. In the latter case the signals can be combined in the output stage to a more complex pattern. In either case, they can be outputted to a single selected output stage or simultaneously to several, either identical or different, output stages.

10 By having a number o signals accessible on the bus, output stages can have simultaneous access to identical or different signals creating the following system configurations:

- 15 A. one selected output stage (either voltage - low or high, current - low or high, or power with a single output producing a simple signal;
one selected output stage providing a single output producing or a complex signal pattern;
- 20 B. one selected output stage with multiple identical outputs (either voltage - low or high, current -

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low or high, or power) with the same shape signals and identical electrical parameters;

one selected output stage with multiple identical outputs with the same shape signals with different amplitudes only

5

C. multiple identical output stages (either voltage - low or high, current - low or high, or power) with the same shape signals with identical electrical parameters;

10

multiple identical output stages with the same shape signals with different amplitudes;

multiple identical output stages with the same shape signals with different timing;

15

multiple identical output stages the same shape signals with different amplitude and timing;

D. multiple identical output stages with different shape signals with all the options from above;

E. multiple identical output stages producing signals with either identical or different complex patterns

20

with all the options from above;

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- F. multiple different output stages, e.g., a low voltage single output stage and multiple current output stage, or a power output stage, producing the same shape signals with identical timing;
- 5 multiple different output stages, producing the same shape signals with different timing;
- multiple different output stages, producing different shape signals with identical timing;
- multiple different output stages, producing
- 10 different shape signals with different timing.

While there has been shown and described preferred embodiments of an multi-functional electrical stimulation system in accordance with the invention, it will be appreciated that many changes may be made therein within the

15 spirit of the invention.

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I CLAIM:

1. A multi-functional electrical stimulation system adapted to produce output signals for effecting faradic, electromagnetic and other forms of electrical stimulation
5 for a broad spectrum of different biological and bio-medical applications, said system being provided with an electrical stimulation signal stage comprising:

A. a plurality of different signal generators, each producing a signal having a distinct predetermined
10 shape;

B. means associated with the generators to adjust the respective timing parameters of the pulse shape including the amplitude and duration of the signal and its repetition rate; and

15 C. selector means coupled to the signal generator to select as an output signal from the electrical stimulation stage the signal yielded by the selected generator.

2. A system asset forth in claim 1, in which one of
20 the generators produces a sine wave.

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3. A system as set forth in claim 1, in which one of the generators produces a square wave.

4. A system as set forth in claim 1, in which one of the generators produces a sawtooth wave.

5 5. A system as set forth in claim 1 in which said means associated with the generators to adjust the timing parameter includes a serial input port.

6. A system as set forth in claim 5, in which said means further includes parallel input ports.

10 7. A system as set forth in claim 1 further including an output stage into which is fed the output signal of the electrical stimulation signal stage, the output stage processing the electrical stimulation signal to provide a signal appropriate to the application for which it is
15 intended.

8. A system as set forth in claim 7, in which the output stage processes the signal to yield a high or low voltage or current output.

20 9. A system as set forth in claim 8, in which the output stage has multiple parallel output terminals.

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10. A system as set forth in claim 1, further including a measuring stage adapted to measure and display the electrical stimulation signal being applied to a substance being treated as well as the outputs of various
5 sensors which sense conditions prevailing in this substance.

11. A system as set forth in claim 10, in which one of said sensors senses pH.

12. A system as set forth in claim 11, in which another of said sensors senses a gas.

10 13. A system as set forth in claim 12, in which the gas is oxygen.

14. A system as set forth in claim 1, in which the generators are formed by integrated circuits.

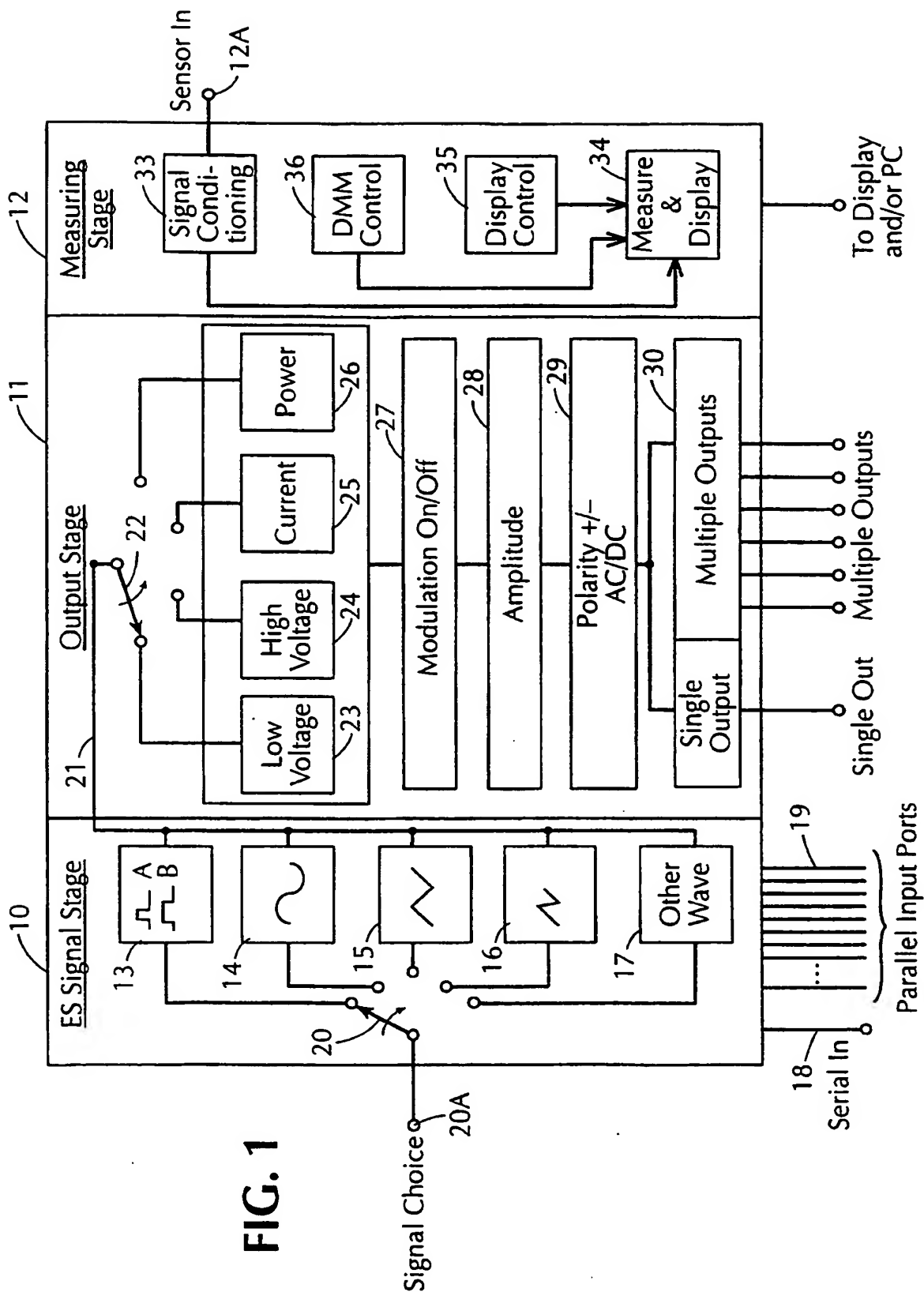


FIG. 1

FIG. 2

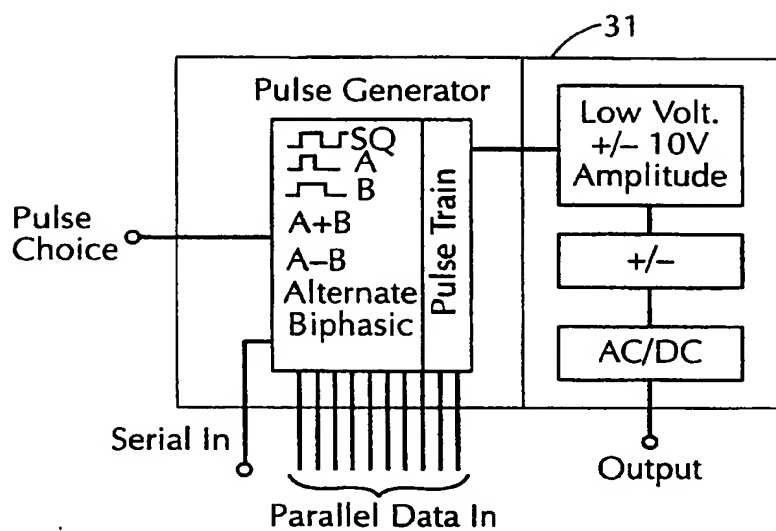


FIG. 3

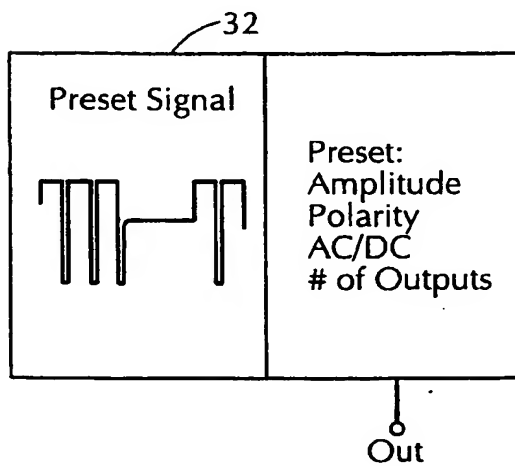
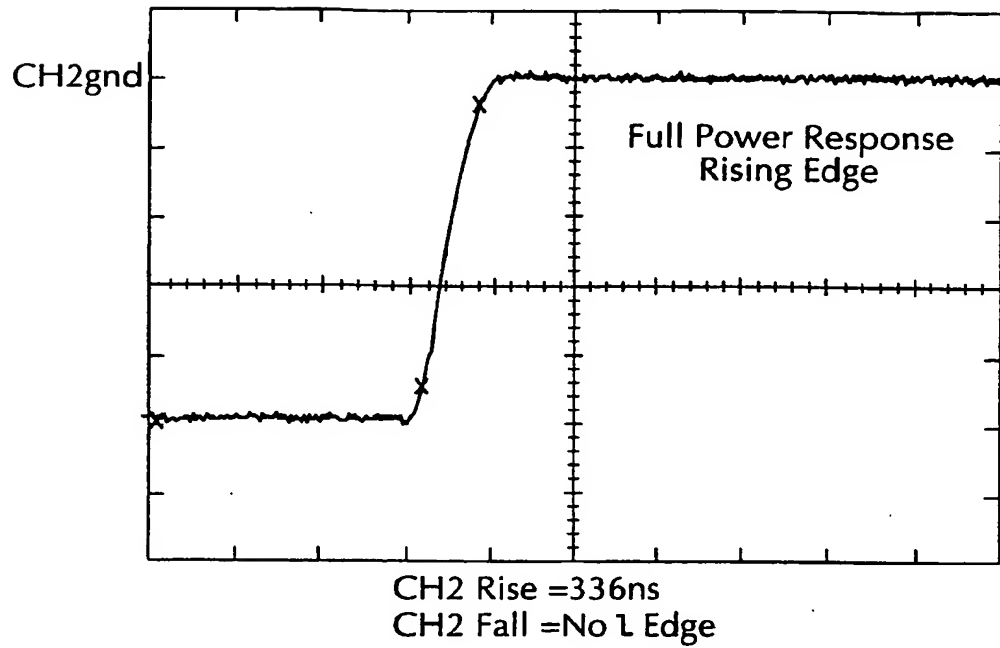
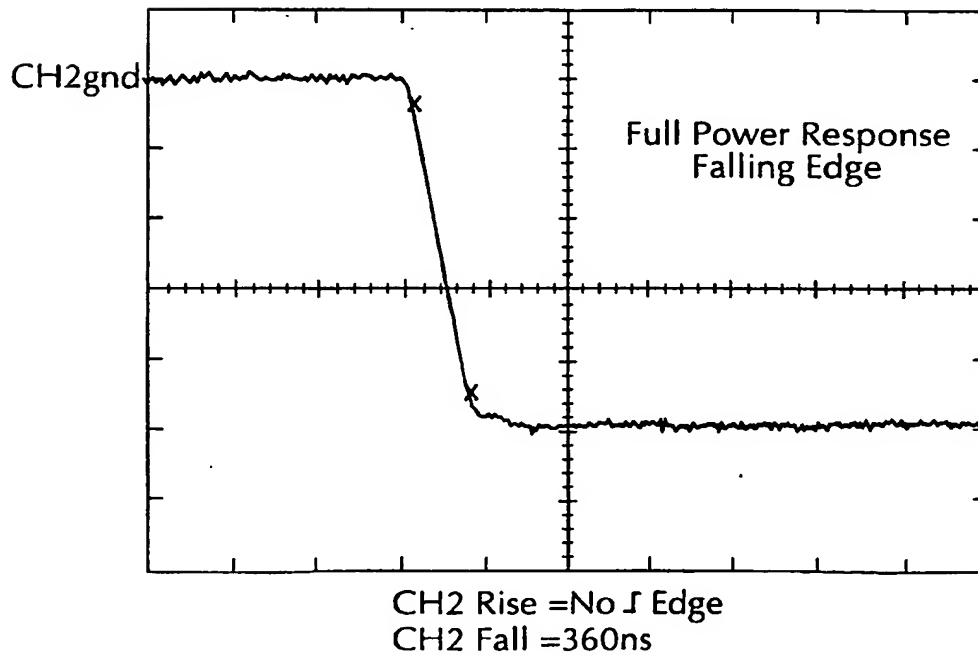


FIG. 4A**FIG. 4B**

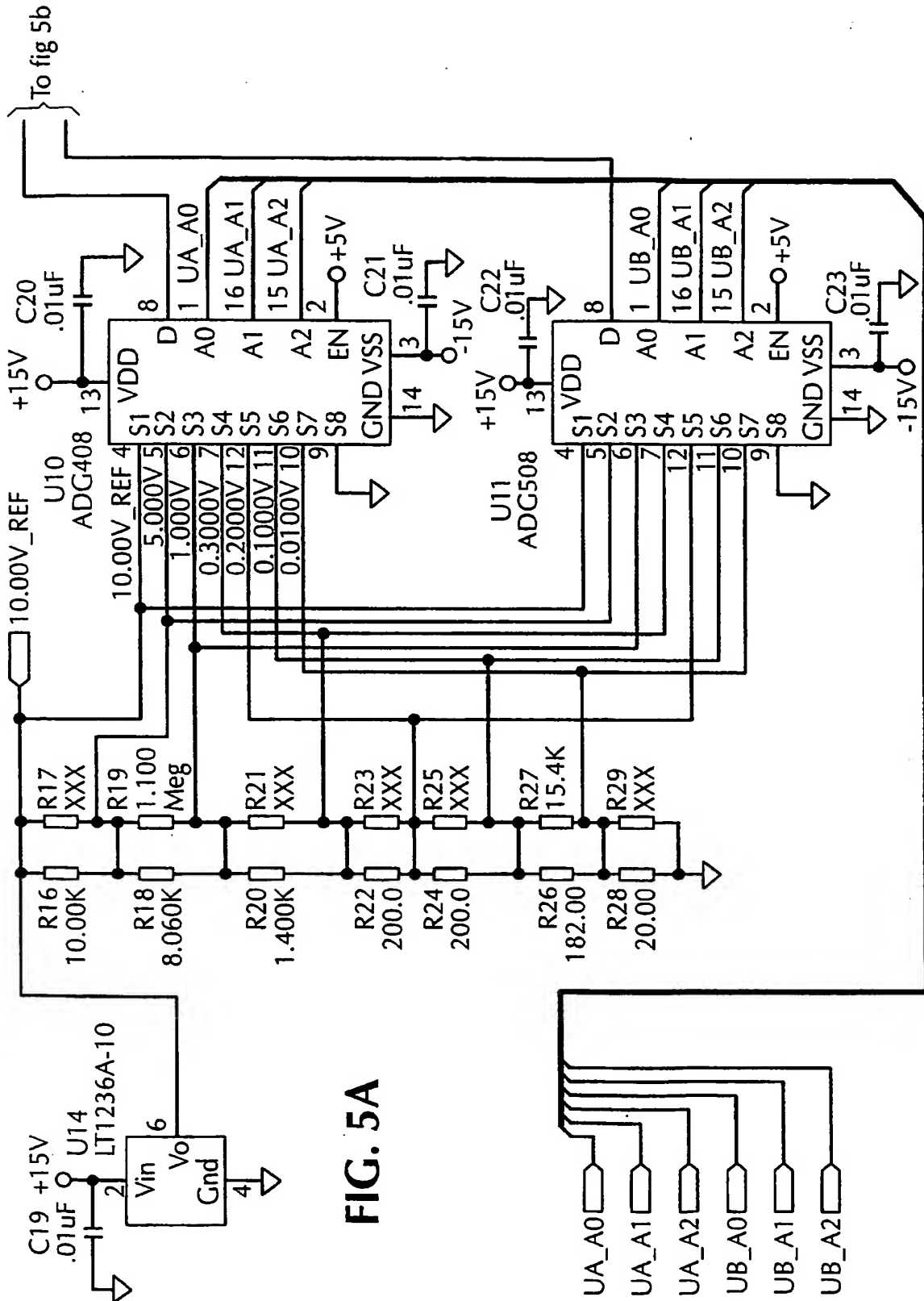


FIG. 5A

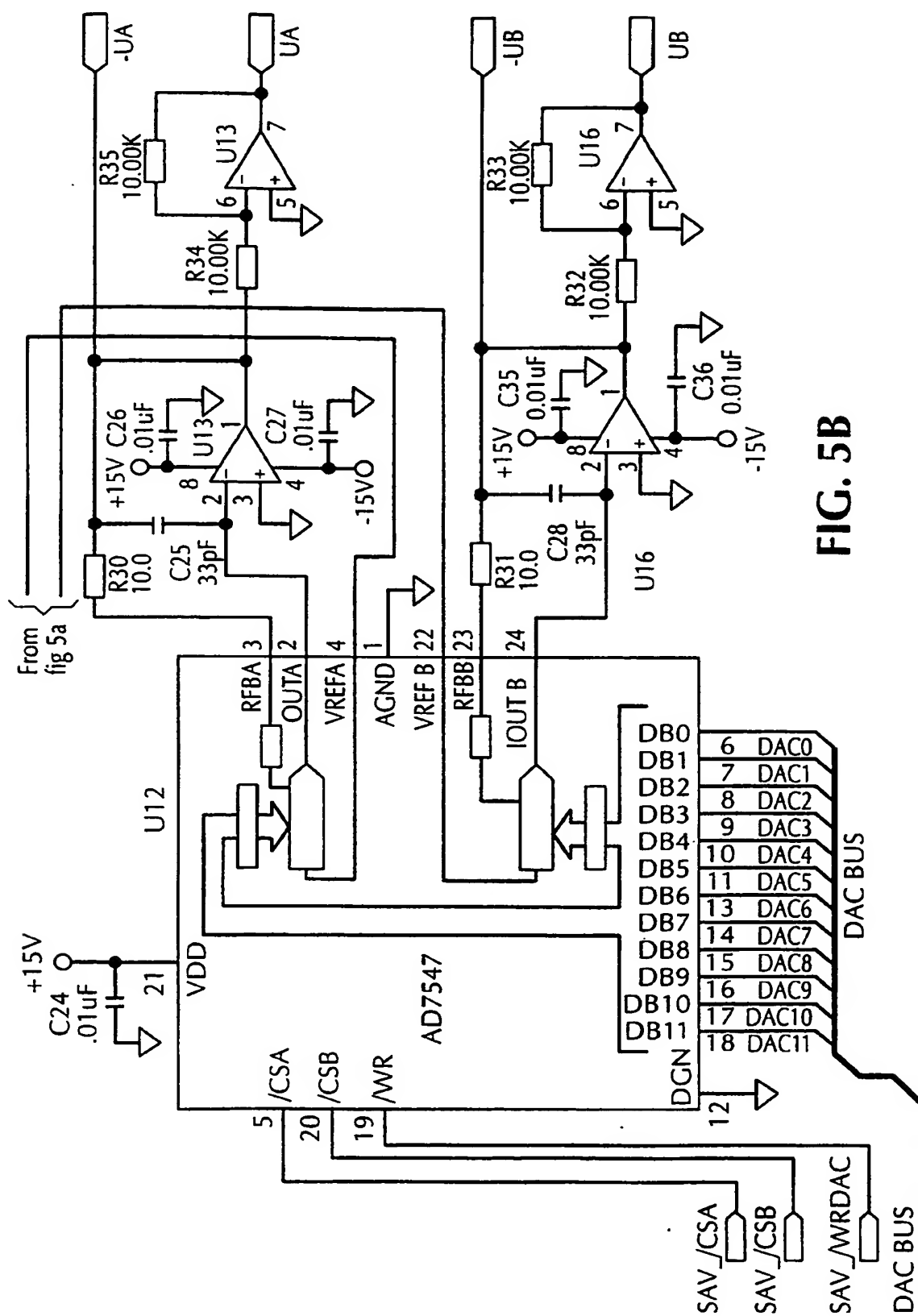
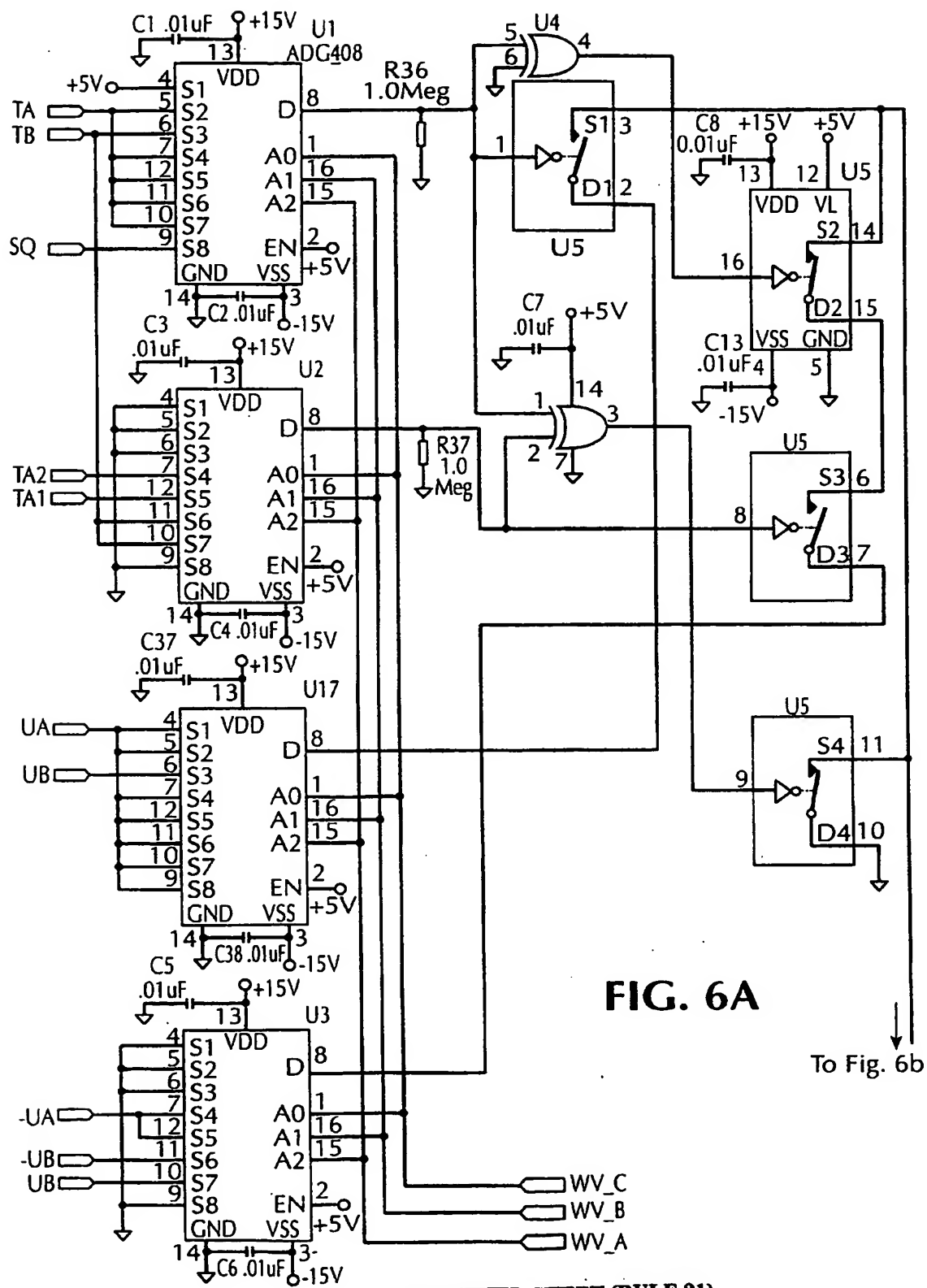


FIG. 5B



To Fig. 6b

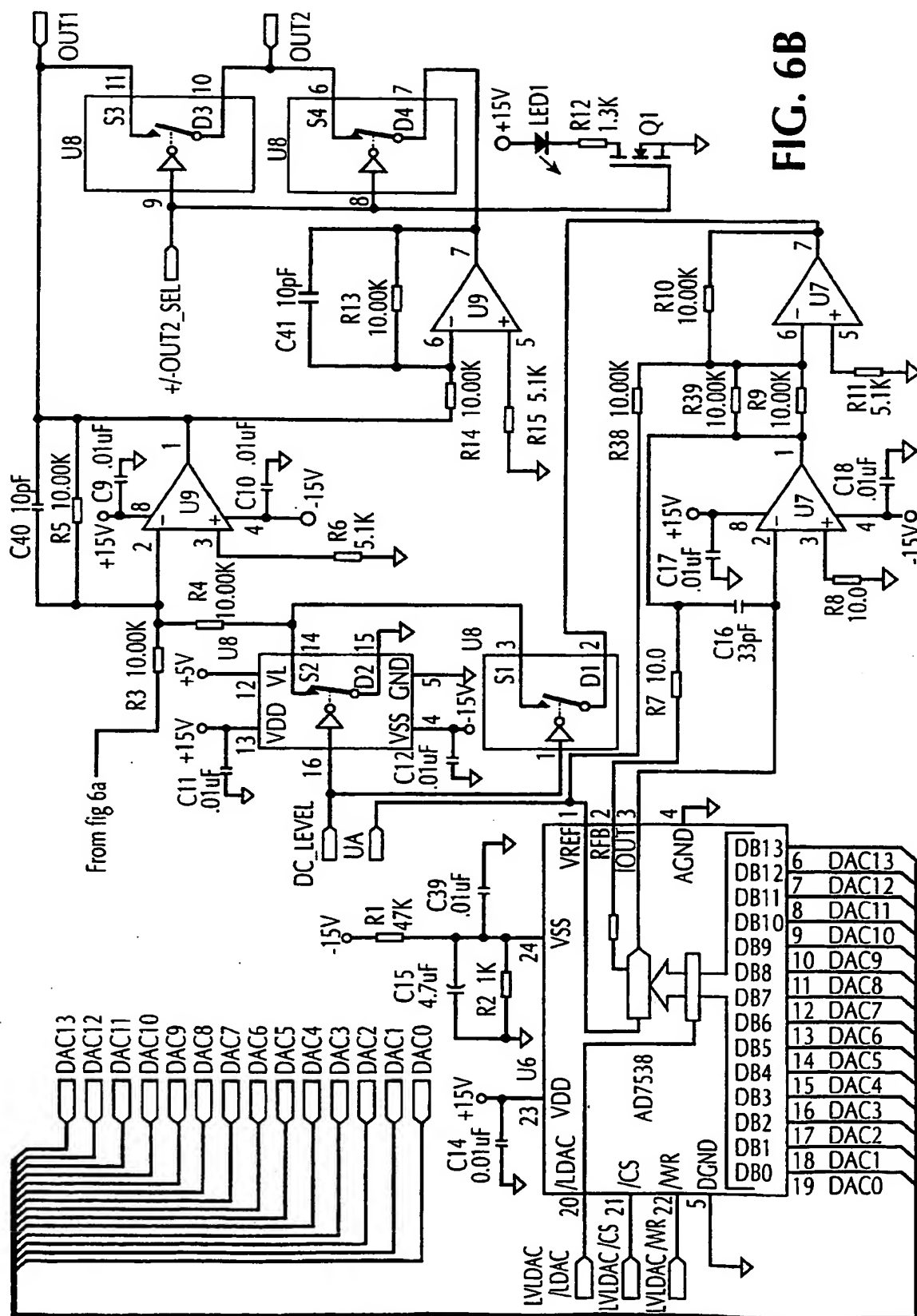


FIG. 6B

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/02036

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61N 1/32

US CL : 607/68

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 607/62, 66, 68

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X — Y	US 4,503,863 A (KATIMS) 12 March 1985, entire document.	1-4 — 5-14

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but used to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

22 MARCH 1999

Date of mailing of the international search report

12 APR 1999

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